

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt. 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

1:13-cv-12682; 1:13-cv-12426; 1:13-cv-12688
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1:13-cv-12580; 1:13-cv-12836; 1:13-cv-12581
1:13-cv-12666; 1:13-cv-12583; 1:13-cv-12734
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1:13-cv-12311; 1:13-cv-12491; 1:13-cv-12998
1:13-cv-12917; 1:13-cv-12619; 1:13-cv-12238

**PLAINTIFFS' STEERING COMMITTEE'S
RULE 56(d) RESPONSE TO TENNESSEE DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT**

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The Plaintiffs' Steering Committee respectfully submits this Rule 56(d) response to the Tennessee Defendants' Motion for Summary Judgment (Dkt. No. 774, the "Motion for Summary Judgment"). On January 10, 2014, the Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Clinic"), Howell Allen Clinic, a Professional Corporation ("Howell Allen"), John Culclasure, M.D. ("Dr. Culclasure"), Debra Schamberg, R.N. ("Ms. Schamberg"), Specialty Surgery Center, Crossville, PLLC ("SSC"), Kenneth R. Lister, M.D. ("Dr. Lister") and Kenneth Lister, M.D., P.C. ("Dr. Lister's Practice") (collectively the "Tennessee Defendants") filed a Motion for Summary Judgment. That Motion requests summary dismissal of 33 individual lawsuits.

The Tennessee Defendants support their Motion for Summary Judgment by relying upon the affidavits of two party defendants, Dr. Culclasure and Dr. Lister. Plaintiffs have not been afforded the opportunity to depose either of those affiants, nor have Plaintiffs been allowed to complete basic discovery. Therefore, the PSC files this Rule 56(d) response and the contemporaneously filed declaration of Benjamin A. Gastel (the "Gastel Decl.") requesting the Court deny the Motion for Summary Judgment and permit the PSC to take discovery in this action prior to addressing the merits of the Motion for Summary Judgment.

I. INTRODUCTION AND BACKGROUND

The Motion for Summary Judgment is untimely, unsupported, and simply unfair. Plaintiffs should be permitted to conduct meaningful discovery before responding to it.

This litigation arises from a widespread outbreak of fungal meningitis affecting victims in at least 20 states. According to the CDC, to date, more than 750 people have been diagnosed with fungal meningitis, fungal infections and/or abscesses. More than 60 people have died.

The fungal infections were caused by a contaminated prescription medication known as methylprednisolone acetate ("MPA"). Pain clinics and hospitals purchased the contaminated

MPA from a compounding pharmacy known as New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center (“NECC”) located in Framingham, Massachusetts. Those same pain clinics and hospitals then sold and distributed that medication to patients. The patients played no role in selecting NECC as the source of the MPA that they received.

According to the CDC, the fungal meningitis outbreak dramatically impacted patients in Tennessee. Tennessee patients comprise 153 confirmed cases of infection and 16 deaths.¹ Of the clinics in Tennessee that purchased and administered tainted NECC products to their patients, Saint Thomas Clinic and SSC administered the overwhelming majority of tainted pharmaceuticals that resulted in confirmed infections and deaths.

The Tennessee Defendants now move this Court for the summary dismissal of 33 lawsuits brought as a result of this national tragedy. They move for summary judgment even though little to no discovery has been conducted. Saint Thomas Clinic and SSC have not fully responded to written discovery. SSC has not produced a single document. Saint Thomas Clinic has produced only limited documents and has refused to produce electronic stored information that it segregated almost a year ago. No depositions have been taken. Both Saint Thomas Clinic and SSC have refused to provide meaningful responses to written discovery.²

Notwithstanding the Tennessee Defendants’ active refusal to participate in meaningful discovery, they now seek summary judgment. In support of their Motion, the Tennessee Defendants tender affidavits made by two party defendants boldly attesting that the Tennessee Defendants “comple[d] with the accepted standard of care for [the administration of epidural steroid injections] in this community.”³ The Tennessee Defendants only offer self-serving

¹ Gastel Decl. at Ex. 4.

² For full explanation of the Plaintiffs’ attempts to obtain discovery over the Tennessee Defendants, *see* Gastel Decl., ¶¶ 4-10 and Exs. 1 and 2.

³ Doc. No. 776, ¶¶ 6-7, Statement of Material Fact (“Dr. Culclasure [and Dr. Lister] followed a procedure that

affidavits in support of this claim. They offer no outside proof and no expert opinion - just the simple and plain statement that they complied with “the accepted standard of care.” In other words, the Tennessee Defendants seek summary judgment on grounds of nothing more than that they, and they alone, believe they did nothing wrong.

The overwhelming majority of the 33 lawsuits in which the Tennessee Defendants request summary judgment were initially filed under Tennessee’s unique Products Liability Act (T.C.A. § 29-28-101, *et seq*), in which breach of the applicable standard of care is not an element. That products liability statute specifically authorizes injured consumers to prosecute products liability claims against sellers and/or distributors of harmful products in certain circumstances, including when a product manufacturer is insolvent.⁴ The language of the Tennessee Products Liability Act expressly contemplates that healthcare providers, like all other sellers, can be subjected to products liability claims.⁵ The applicability of the Tennessee Products Liability Act to these proceedings is the subject of a separate motion to dismiss filed by the same Defendants, and it will be briefed separately in accordance with the parties’ agreed briefing schedule.⁶

The Tennessee Defendants’ present Motion for Summary Judgment principally targets lawsuits in which the initial complaints included products liability claims only. Those initial complaints did not assert claims under the Tennessee Healthcare Liability Act (“THLA”), the statute requiring the Certificate of Good Faith in certain circumstances, which the Tennessee Defendants claim should have been filed with the complaints.⁷ Under the plain language of that

complied with the recognized standard of acceptable professional practice.”).

⁴ T.C.A. § 29-28-106

⁵ *Id.*; *see also* T.C.A. § 29-28-102(7).

⁶ *See* Doc. No. 771.

⁷ *See* T.C.A. § 29-26-122.

statute, plaintiffs asserting claims under the Tennessee Products Liability Act, or other claims unrelated to the whether a defendant satisfied the standard of care, are not required to file a certificate of good faith because that requirement only applies in instances where a complaint requires expert proof regarding the applicable standard of care.⁸ Put differently, two conditions must be satisfied before the obligation to file a certificate of good faith is triggered: 1) plaintiff must make a claim under the THLA; and 2) plaintiff's THLA claim must require expert proof as to the applicable standard of care.⁹ Plaintiffs' claims under the Tennessee Products Liability Act fail both preconditions 1) they are not claims made under the THLA; and 2) they are not claims that require expert proof as to the applicable standard of care.

Certain Plaintiffs initially filed products liability actions only because of unique requirements of Tennessee law. Under the Tennessee Products Liability Act, arguably, a statute of limitations could run one year after purchase of the product at issue.¹⁰ Under the THLA, arguably, a statute of limitations begins to run one year after a party discovers an injury related to the provision of care.¹¹ However, that statute of limitations for claims under the THLA could be extended an additional 120 days if service under T.C.A. § 29-26-121 is given.¹² Further, a party

⁸ See *id.* ("In any health care liability action in which expert testimony is required by § 29-26-115, the plaintiff or plaintiff's counsel shall file a certificate of good faith with the complaint.") On its plain terms then T.C.A. § 29-26-122 does not apply to *all* claims related to patient care, as the Tennessee Defendants would have this court believe. See Dkt. No. 772 at 2-3. Following the Tennessee Defendants' twisted reading of this statute, if a billing dispute between a patient and doctor resulted in a lawsuit, a plaintiff would be required to file a certificate of good faith certifying that the doctor's conduct fell below the applicable standard of care in failing to properly bill a client for a service. Further, if a patient and doctor had a dispute related to a HIPAA violation, then, according to the Tennessee Defendants, that patient would have to file a certificate of good faith certifying that the doctor's conduct fell below the applicable standard of care as it relates to the doctor's HIPAA obligations. These absurd results are avoided if the statute is interpreted as it is written and not as the Tennessee Defendants claim it is written.

⁹ *Id.*

¹⁰ T.C.A. § 29-28-103. The PSC does not concede that this is the proper interpretation of Section 103 and believe that a proper reading of this statute would place the time for the running of the statute much later. Nevertheless, Defendants will likely argue that actions under the TPLA accrued on the date of administration of the product at issue and therefore such claims would expire within 1 year thereafter. T.C.A. § 29-28-103 citing T.C.A. § 28-3-104 (imposing one year statute of limitations for claims under the TPLA).

¹¹ See T.C.A. § 29-26-116 citing T.C.A. § 28-3-104 (imposing one year statute of limitations for claims under the THLA).

¹⁴ See e.g., Complaint ¶¶ 255-258, *Barger v. Ameridose*, Case No. 1:13-cv-12619 (discussing reasons for filing only

must provide notice under the T.C.A. § 29-26-121 at least 60 days prior to filing an action that falls within the coverage of the THLA.¹³ Accordingly, one possible interpretation of these rules is that a products liability action could expire while the 60 day waiting period for filing claims under the THLA has yet to run. As a result, and out of an abundance of caution, some Plaintiffs took a conservative approach and filed claims under the Tennessee Products Liability Act while waiting for the THLA claims to ripen pursuant to the 60 day notice requirement. Many of the original products liability complaints expressly stated they did not contain claims under the THLA, and the plaintiffs reserved their right to amend their pleadings to add claims under the THLA once such claims became ripe.¹⁴

The majority of Plaintiffs subject to the Motion for Summary Judgment that amended their complaints to add claims under the THLA then filed the certificate of good faith. Such Plaintiffs continue to assert products liability claims, THLA claims, and other causes of action not covered by the THLA.¹⁵ Hence, Plaintiffs timely filed a certificate of good faith with the original complaint alleging violations of the THLA.

Therefore, the central question in order to resolve the Motion for Summary Judgment is not whether the Tennessee Defendants are health care providers under the THLA. The central

claims under the TPLA and awaiting sixty day period to run under T.C.A. § 29-26-121); Complaint ¶ 172, *Minor v. Ameridose*, Case No. 1:13-cv-12836 (declining to assert claims under the THLA and reserving right to amend to add claims later).

¹⁴ See e.g., Complaint ¶¶ 255-258, *Barger v. Ameridose*, Case No. 1:13-cv-12619 (discussing reasons for filing only claims under the TPLA and awaiting sixty day period to run under T.C.A. § 29-26-121); Complaint ¶ 172, *Minor v. Ameridose*, Case No. 1:13-cv-12836 (declining to assert claims under the THLA and reserving right to amend to add claims later).

¹⁴ See e.g., Complaint ¶¶ 255-258, *Barger v. Ameridose*, Case No. 1:13-cv-12619 (discussing reasons for filing only claims under the TPLA and awaiting sixty day period to run under T.C.A. § 29-26-121); Complaint ¶ 172, *Minor v. Ameridose*, Case No. 1:13-cv-12836 (declining to assert claims under the THLA and reserving right to amend to add claims later).

¹⁵ See e.g., Amended Complaint, *Barger v. Ameridose*, Case No. 1:13-cv-12619; Amended Complaint, *Minor v. Ameridose*, Case No. 1:13-cv-12836.

¹⁵ See e.g., Amended Complaint, *Barger v. Ameridose*, Case No. 1:13-cv-12619; Amended Complaint, *Minor v. Ameridose*, Case No. 1:13-cv-12836.

question is whether the Tennessee Defendants are “sellers” under Tennessee’s unique products liability statute and whether those defendants are legally required to stand behind the product.¹⁶ To the extent that Plaintiffs can demonstrate that the Tennessee Defendants are “sellers” as that term is used in T.C.A. § 29-28-102(7), then the Tennessee Defendants are liable to Plaintiffs for all harm caused by the product if the conditions for holding sellers liable are satisfied.¹⁷ In other words, the Tennessee Defendants are liable for all harm caused by the drugs that they selected and sold to their patients, regardless of whether they are also liable for medical malpractice under the THLA and regardless of whether Plaintiffs properly followed the THLA’s certificate of good faith requirement.¹⁸ The ability of a plaintiff to plead claims under the Tennessee Products Liability Act and the THLA will be addressed in conjunction with the Tennessee Defendants’ Global Motion to Dismiss¹⁹ and will be briefed separately in accordance with the parties agreed briefing schedule.²⁰

None of this is explicitly spelled out in the Defendants’ Motion for Summary Judgment. That motion is deliberately opaque presumably because the Tennessee Defendants are attempting to confuse the Court about the nature and requirements of Tennessee law. The Tennessee Defendants instead try to make the Motion for Summary Judgment a strict matter under the THLA.²¹ In fact, the vast majority of the complaints they seek to dismiss originally made claims

¹⁶ See T.C.A. § 29-28-102(7); *see also* Dkt. No. 772, Tennessee Defendant’s Memo, In Support of Global Motion to Dismiss, at P. 27 (claiming that “[the Tennessee Defendants] are not “sellers” of the medications they administer.”)

¹⁷ T.C.A. §29-28-106.

¹⁸ Even if some individual plaintiffs failed to follow T.C.A. § 29-26-122 by timely filing a certificate of good faith, and the PSC does not concede that any plaintiffs have failed to do so, any individual inquiry as to whether a plaintiff did or did not satisfy T.C.A. § 29-26-122 is not appropriate at this time. Judge Saylor has already denied the Tennessee Defendants’ attempts to obtain summary judgment in case-specific instances. *See* Dkt. No. 725 (ordering denying motions for summary judgment and listing cases where such motions were filed).

¹⁹ Doc. No. 771 at 3 (asserting that a plaintiff cannot assert claims under the Tennessee Product Liability Act against health care providers).

²⁰ *See* Doc. No. 884.

²¹ *See* Dkt. No. 775 at 2-3.

only under the Tennessee Products Liability Act, not the THLA. That important distinction is never mentioned in Defendants' Motion or the fifteen page Memorandum in support thereof.²² The Tennessee Defendants obfuscate that fact by claiming that the Plaintiffs assert causes of action under both the Tennessee Products Liability Act and the THLA, citing the Master Complaint as the basis for this assertion.²³ This is very misleading. The complaints subject to the Motion for Summary Judgment were all filed before the Master Complaint and therefore could not have asserted the claims contained in the Master Complaint. Although 30 of the 33 cases originally alleged claims only under the Tennessee Products Liability Act, 31 of the 33 cases eventually filed amended complaints adding additional claims. Some plaintiffs added additional common law claims (i.e., civil conspiracy and agency) and some plaintiffs added claims under the THLA. For those plaintiffs adding claims under the THLA subject to the certificate of good faith requirement under T.C.A. § 29-26-122, those plaintiffs then filed the required certificate.

The Tennessee Defendants never make this clear, presumably because to do so, would reveal the futility of their argument. After all, the Motion for Summary Judgment hinges on the idea that Plaintiffs' original (i.e. the first filed) complaint alleged claims under the THLA that were subject to the certificate of good faith requirement under T.C.A. § 29-26-122.²⁴

This Court should ignore the Tennessee Defendants' attempts at distraction. The Motion for Summary Judgment simply cannot be adjudicated until and unless Plaintiffs are permitted to,

²² Dkt. No. 775 at 2-3.

²³ See Dkt. No. 775 at 2 ("The Plaintiffs assert claims styled as health care liability and a variety of alternative theories of liability against the Tennessee Defendants, including...ordinary negligence, Tennessee Consumer Protection Act; Battery; Failure to Warn, Tennessee Products Liability Act of 1978; Agency; Civil Conspiracy.) (citing the Master Complaint).

²⁴ See Dkt. No. 775 at P. 9-10 ("Since all of the Plaintiffs' claims against the Tennessee Defendants are health care liability actions, the Plaintiffs' Complaints are subject to dismissal if they fail to comply with [T.C.A. § 29-26-122]. Each of the Plaintiffs identified in this Motion failed to file a Certificate of Good Faith with their original Complaints." (emphasis added).

at a minimum, depose the affiants and conduct other important discovery. In addition, the Motion for Summary Judgment cannot be adjudicated unless and until this Court rules upon the application of the Tennessee Products Liability Act in conjunction with the Tennessee Defendants' Global Motion to Dismiss.²⁵ Accordingly, the Motion for Summary Judgment is simply premature and should be denied.²⁶

II. RULE 56(D) IS INTENDED TO ALLOW A PARTY FACED WITH A PREMATURE MOTION FOR SUMMARY JUDGMENT TO OBTAIN DENIAL OF THAT MOTION PENDING AN OPPORTUNITY TO TAKE DISCOVERY

Fed. R. Civ. P. 56(d) states:

If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the motion or deny it...

“When properly invoked, Rule 56[d] allows a party opposing summary judgment additional time to conduct discovery on matters related to the motion.”²⁷

“Typically, a successful Rule 56(d) motion must: 1) be timely; 2) be authoritative; 3)

²⁵ See Dkt. No. 771. In support of this Motion to Dismiss, the Tennessee Defendants take the unsupported position that a party cannot both plead claims under the Tennessee Products Liability Act and the THLA. See Dkt. No. 772 at pg. 12-13. The PSC will respond to this motion on March 28, 2014 per the Court's order. See Dkt. No. 884. Given the overlapping issues raised in this Motion for Summary Judgment and in the Tennessee Defendants' Motion to Dismiss (Dkt. No. 771), the PSC, to the extent necessary, incorporates by reference those portions of its response to Dkt. No. 772 into its response here.

²⁶ The Tennessee Defendants may have filed this premature motion for summary judgment to cut off a plaintiff's right to voluntarily dismiss without leave of court under Rule 41 and thereby take shelter in Tennessee's unique savings statute. The Tennessee Defendants have aggressively pursued summary judgment in this matter filing numerous motions for summary judgment, which Judge Saylor denied. See Dkt. No. 725 (ordering denying motions for summary judgment and listing cases where such motions were filed). Tennessee has a unique savings statute that permits a plaintiff to voluntarily dismiss without prejudice and refile the same action within one year when certain conditions are satisfied. See T.C.A. 28-1-105(a). By filing a motion for summary judgment, the Tennessee Defendants effectively cut off a party's right to obtain a dismissal without leave of court and thereby fall within coverage of the savings statute. See *Turner v. Aldor Co. of Nashville, Inc.*, 827 S.W.2d 318 (Tenn. Ct. App. 1991) (discussing purpose of savings statute). Given this, it should come as no surprise that the Tennessee Defendants are seeking once again to file a premature motion for summary judgment. The Tennessee Defendants even acknowledged that its Motion for Summary Judgment could have been filed as a Rule 12 Motion. See Dkt. No. 775 at n. 11. In any event, Judge Saylor previously indicated that motions for summary judgment should be considered in due course, after discovery is completed. This seems a more appropriate method for addressing motions for summary judgment, and the PSC respectfully requests that the Court adopt Judge Saylor's plan in addressing motions for summary judgment.

²⁷ See *C.B. Trucking v. Waste Mgmt.*, 137 F.3d 41, 44 (1st Cir. 1998). (“[D]istrict courts should liberally grant Rule 56 continuances where the Rule's preconditions for relief have been satisfied.” *Pina v. Children's Place*, 2014 U.S. App. LEXIS 1537 (1st Cir. 2014), citing *Simas v. First Citizens' Fed. Credit Union*, 170 F.3d 37, 46 (1st Cir. 1999).

show good cause for failure to discover the relevant facts earlier; 4) establish a plausible basis for believing that the specified facts probably exist, and 5) indicate how those facts will influence the outcome of summary judgment.”²⁸

In short, when faced with a premature motion for summary judgment, Rule 56(d) is meant to provide a non-moving party with an opportunity to present an affidavit to defer considering the motion or deny the motion altogether, when the affidavit establishes a plausible basis for believing that facts exist that will support denial of the motion but the party has not yet had the opportunity to conduct discovery to create such an issue.²⁹

Given that the Plaintiffs here have not had any opportunity to conduct meaningful discovery, and have not had the opportunity to conduct a single deposition (despite repeated requests), the bar for satisfying Rule 56(d) is particularly low. Courts grant almost as a matter of course, Rule 56(d) requests when the nonmoving party has not had the opportunity to conduct discovery.³⁰

III. PLAINTIFFS HAVE DEMONSTRATED THE PRECONDITIONS FOR RULE 56(d) RELIEF ARE SATISFIED

As indicated above, “a successful Rule 56(d) motion must: 1) be timely; 2) be authoritative; 3) show good cause for failure to discover the relevant facts earlier; 4) establish a plausible basis for believing that the specified facts probably exist; and 5) indicate how those

²⁸ *Simas*, 170 F.3d at 45 n.4; *see also Resolution Trust Corp. v. N. Bridge Assocs., Inc.*, 22 F.3d 1198, 1203 (1st Cir. 1994).

²⁹ *See Simas*, 170 F.3d at 46; *Commonwealth Aluminum Corp. v. Markowitz*, 164 F.R.D. 117 (D. Mass 1995) (granting Rule 56d motion for continuance when party presented evidence of a “a plausible basis for a belief that discoverable materials exist that would likely suffice to raise a genuine issue of material fact and, thus, defeat summary judgment.”).

³⁰ *See e.g., Wichita Falls Office Assocs. v. Banc One Corp.*, 978 F.2d 915, 919 n.4 (5th Cir. 1992) (holding that courts grant Rule 56(d) motions “almost as a matter of course unless the non-moving party has not diligently pursued discovery of the evidence.”); *see also Oahn Nguyen Chung v. Studentcity.com, Inc.*, Case No. 10-10943, 2013 U.S. Dist. LEXIS 173911, 4-5 (D. Mass. Dec. 12, 2013) (Zobel, J.) (granting Rule 56(d) relief when no discovery had occurred and noting that “[Rule 56(d)] is intended to safeguard against judges swinging the summary judgment axe too hastily.”)

facts will influence the outcome of summary judgment.”³¹

A. The Timeliness And Authoritativeness Of This Motion And The Inability Of Plaintiffs To Discover Relevant Facts Earlier Cannot Reasonably Be Questioned.

This Rule 56(d) response clearly and unmistakably satisfies the requirements of timeliness. Typically, Rule 56(d) motions are only denied on grounds of untimeliness when Plaintiffs’ counsel have failed to diligently pursue discovery and the discovery period has lapsed or passed by the time a responding party filed a Rule 56(d) response.³² In the present case, discovery has barely begun, let alone concluded.

Plaintiffs have not had any opportunity whatsoever to conduct meaningful discovery, despite their best attempts at actively pursuing discovery to date.³³ The Tennessee Defendants have actively resisted those attempts and even previously moved the Court to stay discovery.³⁴ Accordingly, this Rule 56(d) response is timely and this precondition is easily satisfied.³⁵

Furthermore, counsel for Plaintiffs submit a declaration explaining the basis for believing that additional facts exist for the resolution of the Motion for Summary Judgment.³⁶ Therefore, this Rule 56(d) is unquestionably authoritative.³⁷

Likewise, there is no reasonable basis to dispute the fact that Plaintiffs have good cause to show why the facts have not yet been discovered. Not only have Plaintiffs not had time to fully develop the facts that would allow them to respond to the Motion for Summary Judgment,

³¹ *Simas*, 170 F.3d at 45 n.4; *see also Resolution Trust Corp.*, 22 F.3d 1198 at 1203.

³² *See e.g., Waste Mgmt.*, 137 F.3d at 45 (“[T]he company conducted no discovery on this issue during the twenty-one months in which this case was pending in the district court. Given this failure, C.B. Trucking is in no position to complain of the court’s decision to examine the evidentiary sufficiency of the predatory pricing claim.”).

³³ *See Gastel Decl.*, Ex. 2.

³⁴ Dkt. No. 457 and 459.

³⁵ *See Studentcity.com, Inc.*, 2013 U.S. Dist. LEXIS 173911, 4-5.

³⁶ *See Gastel Decl.*, ¶¶ 11-20.

³⁷ *See Paterson-Leitch Co. v. Massachusetts Municipal Wholesale Elec. Co.*, 840 F.2d 985, 988 (1st Cir. 1988) (“The [Rule 56(d)] statement must be made, if not by affidavit, then in some authoritative manner -- say, by the party under penalty of perjury or by written representations of counsel subject to the strictures of Fed. R. Civ. P. 11 - and filed with the court.”)

but the Tennessee Defendants, as discussed above, actively refused to give them that opportunity. Accordingly, there is no meaningful dispute that the Plaintiffs have good cause for why they need more discovery to fully respond to the Motion for Summary Judgment.³⁸

B. The Gastel Affidavit Establishes The Likely Existence Of Facts That Would Justify Denying The Motion For Summary Judgment.

1. Plaintiffs Must Be Permitted Opportunity to Discovery Facts To Support The Tennessee Defendants' Liability Under the Tennessee Products Liability Act.

As indicated above, the Court must resolve whether the Tennessee Defendants are “sellers” of NECC tainted pharmaceuticals as that term is used in the Tennessee Products Liability Statute. A seller is defined as “a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale, or for use or consumption.”³⁹

The Plaintiffs reasonably believe that discovery will establish that the Tennessee Defendants are an “entity” engaged in the selling or distributing of NECC tainted pharmaceuticals for use or consumption.⁴⁰ Discovery should be permitted to allow Plaintiffs an opportunity to establish that:

- The Tennessee Defendants sold and distributed pharmaceuticals used in epidural steroid injections;
- The Tennessee Defendants charged patients and their insurers separately for the drugs sold. In other words, the Tennessee Defendants billed Medicare, United Healthcare, and other payers for the subject steroids separate and apart from the service of administering those steroids. Such discovery is central to establishing

³⁸ See *Studentcity.com.*, 2013 U.S. Dist. LEXIS 173911, 4-5.

³⁹ T.C.A. § 29-28-102(7).

⁴⁰ See *Id.*

that the Tennessee Defendants were “sellers” under the Tennessee Products Liability Act. In other words, the manner in which the Tennessee Defendants billed for and were paid for the product indicates that they sold it to patients.⁴¹

- The NECC products the Tennessee Defendants sold to their patients were in a defective condition or were unreasonably dangerous at the time they left the control of the Tennessee Defendants;
- The tainted pharmaceuticals the Tennessee Defendants sold to patients caused serious injuries, including serious fungal meningitis infections, and in some instances death.

There is a reasonable basis to believe that such facts could be supported with admissible evidence if and when Plaintiffs are permitted to actually conduct discovery.⁴² Establishment of such facts would, at a minimum, require that Plaintiffs’ claims under the Tennessee Products Liability Act survive the Motion for Summary Judgment. Therefore, Plaintiffs satisfy the preconditions for relief under Rule 56(d).⁴³

2. Plaintiffs Must Be Permitted Opportunity to Discovery Facts To Support The Tennessee Defendants’ Liability For Civil Conspiracy

As outlined in the Amended Master Complaint and the Gastel Decl., evidence exists that Saint Thomas Clinic actively participated with NECC in skirting the individual-prescription requirements under Massachusetts law.⁴⁴ For example, as Saint Thomas Clinic acknowledged in sworn discovery responses, in early to mid-2012, an NECC representative informed Ms.

⁴¹ This is not to say this is the only method by which Plaintiffs could prove that the Tennessee Defendants are “sellers” of the products at issue. Other evidence likely exists that will also shed light on the extent of the Tennessee Defendant’s activities in selling NECC products, but only through discovery can Plaintiffs identify such evidence. To date, the limited billing records the PSC has been able to review would support Plaintiffs’ claims that the Tennessee Defendants are “sellers.”

⁴² Gastel Decl., at ¶¶ 11-15.

⁴³ See *Studentcity.com, Inc.*, 2013 U.S. Dist. LEXIS 173911, 4-5.

⁴⁴ Gastel Decl., ¶¶ 15-17 and Amended Master Complaint, Dkt. No. 832 and 832-2 and 3.

Schamberg, one of the Tennessee Defendants that NECC needed to receive lists of patients with each order for MPA.⁴⁵ The NECC representative explained that NECC needed those lists in order to comply with Massachusetts Board of Pharmacy requirements.⁴⁶ Evidently, Ms. Schamberg then told the NECC representative that she could not predict which patients would receive MPA and therefore could not provide lists that would actually correspond with patients who receive MPA.⁴⁷ In response, the NECC representative indicated that any list of patient names would suffice.⁴⁸ In response to NECC's request for assistance in papering over Massachusetts Board of Pharmacy requirements, Saint Thomas Clinic sent NECC lists of patients' names and addresses even though the listed patients did not necessarily receive MPA.⁴⁹ At least one of those lists contained fictitious names, including Mickey Mouse.⁵⁰

SSC has not produced a single document in this litigation, and so it is unclear the extent to which SSC also participated in the civil conspiracy scheme outlined in the Master Complaint. Based on documents produced by other clinics involved in this litigation, other clinics also participated in this scheme, and documents likely exist that will show SSC also participated in this conspiracy.⁵¹

As detailed above, to the extent that the Tennessee Defendants were engaged in an active civil conspiracy to aid NECC and its agents in evading Massachusetts Board of Pharmacy regulations, then the Tennessee Defendants are liable for civil conspiracy, regardless of whether they are additionally liable under the Tennessee Products Liability Act and/or the THLA.

⁴⁵ Gastel Decl., ¶ 16.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Amended Master Complaint, Dkt. No. 832 at ¶ 378.

⁵⁰ *Id.*

⁵¹ Gastel Decl., ¶ 17

Accordingly, establishment of such facts would, at a minimum, require that Plaintiffs' claims for civil conspiracy survive the Motion for Summary Judgment. Therefore, Plaintiffs satisfy the preconditions for relief under Rule 56(d).⁵²

3. Plaintiffs Must Be Permitted Opportunity to Discovery Facts To Support The Tennessee Defendants' Liability Under the THLA.

As previously mentioned, the Tennessee Defendants support their Motion for Summary Judgment with unilateral and unsupported declarations that both Saint Thomas Clinic and SSC satisfied the standard of care in providing their patients with tainted NECC products.⁵³ By placing that bold and unsupported assertion in its Statement of Material Fact, the Tennessee Defendants acknowledged that the Motion for Summary Judgment cannot be adjudicated unless and until Plaintiffs have an opportunity to cross examine the affiants' opinions that they "complied with the recognized standard of acceptable professional practice."⁵⁴ This bold claim is supported by nothing more than self-serving affidavits from the very physicians whose conduct is in question. In other words, the Tennessee Defendants believe they are entitled to summary judgment because they, and they alone, say so. They offer no independent, expert opinion and no underlying proof.⁵⁵

Obviously, Plaintiffs asserting claims under the THLA maintain that the Tennessee Defendants cannot demonstrate that they acted in accordance with the recognized standard of

⁵² See *Studentcity.com, Inc.*, 2013 U.S. Dist. LEXIS 173911, 4-5.

⁵³ Doc. No. 771 at ¶ 9, Declaration of Dr. Culclasure ("The procedure I have described for an epidural steroid injection complies with the accepted standard of care for those procedures in this community."); Doc. No. 778-1 at ¶ 9, Declaration of Dr. Lister (same); Doc. No. 776 at ¶¶ 6-7, Statement of Undisputed Facts ("Dr. Culclasure [and Dr. Lister] followed a procedure that complied with the recognized standard of acceptable professional practice")

⁵⁴ Doc. No. 776 at ¶¶ 6-7.

⁵⁵ The Tennessee Defendants possibly included this bold and unsupported allegation in its Statement of Material Fact to circumvent the expert disclosure requirements of Rule 26. As the Court is well aware, expert discovery is normally conducted after the completion of fact discovery but before trial. See Rule 26(a)(2)(D). However, by placing this unsupported statement in their Statement of Material Facts, plaintiffs may be required to produce an expert report prematurely, which would give the Tennessee Defendants an opportunity to see plaintiff's expert report prior to their own witnesses being deposed. The Court should not countenance such tactics, and this alone should justify granting Plaintiffs relief under Rule 56(d).

acceptable professional practice. That inquiry under the THLA requires expert proof and expert discovery has not even commenced.⁵⁶

The fact that discovery is needed to respond to the Tennessee Defendant's bold and unsupported allegation that they satisfied the standard of care almost goes without saying. In a remarkably similar situation in a medical malpractice case, the Tennessee Court of Appeals addressed the same issue where a physician filed early in litigation - before discovery was completed - a self-serving affidavit claiming that the physician satisfied the standard of care.⁵⁷ In overturning the trial court's decision to grant summary judgment on a record containing only a self-serving affidavit from a physician, the Court of Appeals held:

In the instant case, the defendant is attempting to meet his [summary judgment] burden by way of his affidavit and the affidavit of [another physician]. The trial court appears to have decided that the plaintiff should be precluded from testing the truthfulness and accuracy of the testimony of these affiants until such time as she can produce countervailing facts from sources other than [affiant's own testimony]. The problem with this approach is that it forces the plaintiff to accept the defendant's supporting affidavits at face value. This puts the proverbial cart before the horse. What if the defendant's supporting affidavits are not truthful? What if the opinions expressed in them are based on erroneous facts? Since it is the defendant-and not the plaintiff-who has the initial burden on summary judgment, generally speaking **the plaintiff has the right to test the defendant's supporting affidavits by careful cross-examination during a discovery deposition.** If, as is sometimes the case, the plaintiff, through vigorous cross-examination, can completely destroy the effectiveness of the defendant's affidavits, he or she will not be required to present countervailing materials because there will be nothing to rebut and the motion will fail by its own deficiency. While this may not happen often, a plaintiff has the right to try. **Thus, the plaintiff in the instant case has the right to discover the doctors whose affidavits are being used to block the plaintiff's attempt to present her case to a jury.**⁵⁸

⁵⁶ T.C.A. § 29-26-115.

⁵⁷ *Conger v. Gowder*, 2001 WL 301155 (Tenn. Ct. App. 2001).

⁵⁸ *Id.* (emphasis added internal citations omitted).

In other words, under Tennessee law as it relates to establishing whether the applicable standard of care has been met, a defendant cannot simply rely on a self-serving affidavit when the plaintiff has not had the opportunity to depose the affiant and test the sufficiency of claims made therein.⁵⁹

Moreover, establishing a breach of the applicable standard of care, Plaintiffs must tender an expert report establishing what the standard of care is and what actions the Tennessee Defendants' took in breach thereof.⁶⁰ Without full written discovery and deposing the individuals whose conduct is at issue, Plaintiffs cannot reasonably be expected to produce an expert report on the applicable standard of care and the Tennessee Defendants' breach thereof.

Since discovery has barely been commenced, expert discovery has not commenced at all, and no depositions whatsoever have taken place, Plaintiffs have not been afforded the opportunity to develop their claims under the THLA. The Tennessee Defendants' attempts to obtain summary judgment at this early stage must be denied.⁶¹

IV. CONCLUSION

As demonstrated above, the Motion for Summary Judgment is based on facts that the Plaintiffs dispute. Plaintiffs should be given the opportunity to conduct meaningful discovery before responding to the Motion for Summary Judgment. Accordingly, under Rule 56(d)(1), the Court should deny the Motion for Summary Judgment and allow this case to proceed with full discovery before a substantive response to the motion is required.

⁵⁹ See *id.*; see also *Grisham v. McLaughlin*, 2006 WL 1627274 (Tenn. Ct. App. 2006) (overturning grant of summary judgment in medical malpractice claim because "patients [in medical malpractice actions] have a right to sufficient time for discovery in order to obtain the evidentiary materials needed to oppose a summary judgment motion.").

⁶⁰ T.C.A. § 29-26-115; see also *Gunter v. Lab. Corp. of Am.*, 121 S.W.3d 636, 640 (Tenn.2003); *White v. Vanderbilt Univ.*, 21 S.W.3d 215, 226 (Tenn.Ct.App.1999).

⁶¹ See *Studentcity.com, Inc.*, 2013 U.S. Dist. LEXIS 173911, 4-5.

To the extent the Court is not willing to deny the Motion for Summary Judgment outright, Plaintiffs respectfully request that the Court permit them the opportunity to brief the merits of the motion, or the lack thereof, more fully. Plaintiffs maintain that, regardless of whether discovery is required in order to respond to the Motion for Summary Judgment, the Motion is legally without merit and should be decided in conjunction with the agreed briefing schedule applicable to the Tennessee Defendants' Global Motion to Dismiss.⁶²

⁶² Currently, the PSC's response to this Global Motion to Dismiss is due March 28, 2014. If the Court is unwilling to immediately deny the Motion for Summary Judgment under Rule 56(d)(1), then the PSC would respectfully request the Court permit the PSC to fully respond to the Motion for Summary Judgment by March 28, 2014, or by a later date depending on the timing of the Court's ruling on this Rule 56(d) response. Relatedly, to the extent that a full response under Local Rule 56.1 is due with this response, for the reasons stated herein, the PSC respectfully requests the same extension to provide a formal response to the Tennessee Defendant's Statement of Material Fact.

Dated: February 24, 2014

Respectfully submitted,

/s/ J. Gerard Stranch, IV

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CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: February 24, 2014

/s/ J. Gerard Stranch, IV
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